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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A., Plaintiffs and Counterclaim-Defendants, v. MYLAN PHARMACEUTICALS INC., Defendant and Counterclaim-Plaintiff.	:	Civil Action No. 3:11-CV-02506-JAP-TJB **PLAINTIFFS' REPLY CLAIM CONSTRUCTION BRIEF**

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

PRELIMINARY STATEMENT

Scrambling to strengthen its claim construction case, Mylan introduces new arguments in its responsive claim construction brief that should have been set forth, if anywhere, in its opening papers. In relation to "enteric coating layer" ('994), Mylan advances a claim construction (and cites to intrinsic and extrinsic evidence) that it never previously disclosed – in the claim construction exchanges required by the Local Patent Rules, the Joint Claim Construction Statement and/or its opening Markman brief. Likewise, with respect to "enteric coating agent" and "sustained-release agent" ('994), Mylan now identifies purported support in the file history for its contention that those terms must have "separate and distinct" constructions. As for "permits to obtain reduced pH influence in the digestive tract" ('632) and "permits to obtain . . . reduced influence of viscosity" ('632), Mylan articulates, for the very first time, its rationale as to why those terms are purportedly indefinite; oddly enough, Mylan ignores the clear dictates of the intrinsic evidence and applies a "one size fits all" approach that advances the same indefinite argument for both limitations.

Mylan's gamesmanship should not be countenanced. Accordingly, Plaintiffs respectfully request that the Court strike[1] the following new arguments from Mylan's responsive brief (and supplemental expert declaration in support thereof):

- Mylan's argument that "enteric coating layer" ('994) must be an admixture of an enteric coating agent and sustained-release agent (Def.'s Resp. Br. at 14-20) and supporting paragraphs and exhibits from the Supplemental Declaration of Dr. Russell J. Mumper (¶¶35-44, 46-47; Exhibits 22-28);

- Mylan's indefiniteness argument regarding "permits to obtain reduced pH influence in the digestive tract" (Def.'s Resp. Br. at 26-28) and supporting paragraphs from the Supplemental Declaration of Dr. Russell J. Mumper (¶¶50-53);

[1] Plaintiffs direct the Court to the cover letter submitted herewith in relation to its motion to strike.

- Mylan's indefiniteness argument regarding "permits to obtain . . . reduced influence of viscosity" (Def.'s Resp. Br. at 29-30) and supporting paragraphs from the Supplemental Declaration of Dr. Russell J. Mumper (¶¶50, 54-56);

- Mylan's argument that the '994 file history purportedly supports that the "enteric coating agent" and "sustained-release agent" must have "separate and distinct" claim constructions (Def.'s Resp. Br. at 14) and supporting paragraphs and exhibits from the Supplemental Declaration of Dr. Russell J. Mumper (¶¶32-34, 45; Exhibits 23-25).

In the event that the Court decides to entertain Mylan's new arguments, Plaintiffs respectfully request that the Court level the playing field by considering Plaintiffs' rebuttals to Mylan's new arguments, as set forth in further detail below.[2]

ARGUMENT

I. The Court Should Reject Mylan's New Argument That "An Enteric Coating Layer" ('994) Is Limited To An Admixture

Until its responsive Markman brief, Mylan at no point advanced a claim construction for "an enteric coating layer." (*See e.g.*, Joint Claim Constr. Chart (D.I. 59) at 11 (no proposed construction by Mylan and no citation to supporting intrinsic/extrinsic evidence).) Mylan did not even bother to address this term in its opening brief. But now, with five pages of briefing and 12 paragraphs of supporting expert opinion, Mylan seeks to unilaterally inject a limitation into "enteric coating layer" such that it is required to be an admixture of an enteric coating agent and sustained-release agent. The Court should reject Mylan's belated attempt to manufacture a claim construction dispute where there is none.[3]

[2] Plaintiffs also include a Second Supplemental Declaration from its expert, Dr. Stephen R. Byrn, to support Plaintiffs' Reply Claim Construction Brief and to rebut new opinions made by Mylan's expert, Dr. Mumper, in his Supplemental Declaration.

[3] *See* Pls.' Resp. Br. at 8-9 ("Since Mylan does not even address Takeda's proposed construction of this term in its opening brief, it is reasonable to assume that there is no meaningful dispute on this issue.")

A. During Prosecution, The Patentee Did Not Limit "Enteric Coating Layer" To An Admixture Of "Enteric Coating Agent" And "Sustained-Release Agent"

In purported support of its newly-minted construction that the "enteric coating layer" must be an admixture of the "enteric coating agent" and "sustained release agent," Mylan points to the file history. In particular, Mylan focuses on a declaration submitted by the named inventor Shimizu to the PTO that demonstrated the superior qualities of the '994 invention; in that declaration, Shimizu compared Example 9 from the '994 patent with a prior art tablet. (*See* ***Ex. 14***.) Mylan argues that the inventor "represented to the PTO that the claimed invention consisted of fine granules coated with a blend of an 'enteric coating agent' and 'sustained release agent' to form an 'enteric coating layer.'" (Def.'s Resp. Br. at 17 (emphasis added).) Mylan mischaracterizes the file history.

Contrary to Mylan's assertion, neither the patentee nor the inventor limited the "enteric coating layer" to an admixture during prosecution. It is significant that Mylan can point to no express representation made by Shimizu or the patentee that (1) limits the invention to Example 9 (with its blend of an enteric coating agent and sustained-release agent); or (2) requires the "enteric coating layer" of the invention be an admixture or blend of an "enteric coating agent" and a "sustained-release agent." Indeed, since the prior art tablet only included an enteric coating agent, there was no need for Shimizu or the patentee to limit the invention as Mylan suggests in order to overcome that prior art. Instead, during prosecution, the patentee and Shimizu required only that the "enteric coating layer" comprise an enteric coating agent and a sustained-release agent.

Given that the patentee and inventor did not limit the "enteric coating layer" to any specific process or method by which it is made, Mylan's attempt to limit the "enteric coating layer" to just a blend is improper. The Federal Circuit has held that "[t]he method of

manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process" and that "[a] novel product that meets the criteria of patentability is not limited to the process by which it was made." *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372-73 (Fed. Cir. 2000). The Court should reject Mylan's proposed construction.

B. Plaintiffs' Expert Testified That "Enteric Coating Layer" Is Not Limited To An Admixture Of "Enteric Coating Agent" And "Sustained-Release Agent"

Mylan next argues that Plaintiffs' expert, Dr. Byrn, admitted that the "enteric coating layer" must be an admixture of an enteric coating agent and sustained-release agent. (Def.'s Resp. Br. at 15-16.) Not only does Mylan mischaracterize Dr. Byrn's Declaration, but Mylan also conveniently ignores Dr. Byrn's deposition testimony to the contrary.

Mylan identifies a purported admission in Dr. Byrn's declaration: "[T]he '994 patent teaches an enteric coat made from a blend of enteric-coating agent and sustained-release agent . . . ." (Byrn Decl. at ¶ 20.) Yet, nowhere in his declaration – or during his deposition – did Dr. Byrn state that the '994 patent claims are limited to an enteric coating layer that consists of such a blend or admixture. (Byrn Second Supp. Decl. at ¶16.)

In fact, although Mylan attempts to pitch Dr. Byrn's deposition as favorable to it, Mylan ignores Dr. Byrn's unambiguous deposition testimony making clear that the enteric coating layer is not limited to a blend or admixture. (***Ex. 35***, Byrn Dep. Tr. 253:3-6 ("The combination of coatings, two compositions, like are said in the claims, avoid the problems. So the claims say they don't require an admixture."); Byrn Dep. Tr. 254:6-9 ("Well, in the examples he used one method of doing the claim. But that doesn't mean that there aren't other methods, and the examples are not limiting.").)

In short, Mylan's attempt to manufacture a claim construction dispute in relation to "enteric coating layer" – based on mischaracterizations of the file history and Takeda's expert's testimony – should be rejected.

II. The Court Should Reject Mylan's New Arguments That The '632 Claim Terms "Permits To Obtain Reduced pH Influence In The Digestive Tract" And "Permits To Obtain . . . Reduced Influence Of Viscosity" Are Indefinite

It is Mylan's burden to prove, by clear and convincing evidence, that the claims are invalid for indefiniteness. It is not Plaintiffs' burden to prove the contrary. And yet, Mylan did not articulate any indefiniteness arguments in its opening brief. This fact, in and of itself, is indicative of how much weight this Court should give to Mylan's new indefiniteness arguments, which Plaintiffs nonetheless rebut below.

A. The Term "Permits To Obtain . . . Reduced Influence Of Viscosity" Means "The Formulation Influences Viscosity Less Than the Prior Art Formulations Of Record That Have Excipients Increasing Viscosity"

This Court has already concluded in *Zydus* that the file history dictates a construction for "permits to obtain . . . reduced influence of viscosity"; thus, the Court construed that term to mean "the formulation influences viscosity less than prior art formulations of record that have excipients increasing viscosity." (***Ex. 27***, Claim Constr. Op. at 12-13.)

Based on Dr. Mumper's conclusory opinions, Mylan insists that this limitation is indefinite. But Dr. Mumper's opinions are inherently flawed; he recognized the significance of critical intrinsic evidence (upon which the Court based its construction) but, nevertheless, rejected it. Thus, Dr. Mumper admitted at his deposition that the patentee incorporated this limitation to distinguish over prior art formulations that contained excipients which increased viscosity. (***Ex. 34***, Mumper Dep. Tr. 110:16-21 ("Yes, I recall in the prosecution history that this

claim term was included to differentiate the '632 claim from prior art that . . . included an excipient that increased the viscosity.").)

Mylan argues that the phrase is indefinite because a person of ordinary skill in the art would not know "what the starting and end points are" and because the "'reduced influence of viscosity' must be relative to some initial viscosity." (Def.'s Resp. Br. at 29-30.) And yet, a claim is not required to quantify the "amount" or "degree" of the reduction for it to be definite, especially where, as here, there is a clear point of comparison. *Pfizer Inc. v. Teva Pharm. USA, Inc.*, Nos. 08-1331, 08-2137, 10-3246, 10-3250 (DMC)(JAD), 2012 WL 1232302, at *11-12 (D.N.J. Apr. 12, 2012) (rejecting argument that the term "reduced undesirable side effects" is indefinite because it is unclear as to the amount of reduction required and whether the reduction must be made to the number of side effects, to the degree of side effects, or both, especially where "proposed construction . . . provide[s] a clear point of comparison for the 'reduced side effects,' in that they are reduced in comparison to the immediate release formulation of the invention") (emphasis added); *Allergan, Inc. v. Watson Labs., Inc.-Fla.*, No. 09-cv-511 (GMS), 2012 WL 1133684, at *34-35 (D. Del. Mar. 31, 2012) (finding disclosure of a point of comparison sufficient to render the claim term "minimizing the occurrence of side effects" definite, rejecting contention that the claim term is indefinite because it did not quantify the amount of minimization). Indeed, the '632 prosecution history identified that point of comparison by establishing that the claimed tablet influences the viscosity of water less than certain prior art formulations that require excipients to increase the viscosity of water. (Byrn Decl. at ¶¶63-70.)

In sum, Mylan's indefiniteness argument has no merit and should be rejected.

B. The Term "Permits To Obtain Reduced pH Influence In The Digestive Tract" Means "The Active Ingredient In The Tablet Is Less Influenced By Stomach pH (*i.e.*, The Drug Is Coated)"

Mylan fails to meet its burden to prove that the phrase "permits to obtain reduced pH influence in the digestive tract" is indefinite. "[T]he definiteness of claim terms depends on whether those terms can be given any reasonable meaning." *Young v. Lumenis, Inc.*, 492 F.3d 1336, 1346 (Fed. Cir. 2007) (emphasis added) (citation omitted). "If the meaning of the claim is discernible, even though . . . the conclusion may be one over which reasonable persons will disagree . . . the claim [is] sufficiently clear to avoid invalidity on indefiniteness grounds." *Exxon Research & Eng'g Co. v. U.S.*, 265 F.3d 1371, 1375 (Fed. Cir. 2001) (emphasis added).

As discussed at length in Plaintiffs' claim constructions briefs, and as explained by Plaintiffs' expert, Plaintiffs' proposed construction ("the active ingredient in the tablet is less influenced by stomach pH (*i.e.*, the drug is coated)") is reasonable given the '632 patent's clear teaching of a tablet that contains coated, gastroresistant drug granules. In stark contrast, Mylan submits its expert's conclusory opinion that there is "no correlation . . . between reduced pH influence in the digestive tract and gastroresistance." (Mumper Supp. Decl. at ¶53.)

Applying a "one size fits all" approach, Mylan advances an indefiniteness argument for "permits to obtain reduced pH influence in the digestive tract" that is the same as its indefiniteness argument for "permits to obtain . . . reduced influence of viscosity." (*Compare, e.g.*, Def.'s Resp. Br. at 27, *with* Def.'s Resp. Br. at 29 (critiquing limitations because there is no "starting point and ending point").) This approach is consistent with Mylan's general disregard of the intrinsic evidence. Mylan makes no allowances for the fact that each term is associated with a distinct file history that bears on claim construction – indeed, the Court adopted a claim construction for "permits to obtain . . . reduced influence of viscosity" based on the file history.

Mylan's arguments that the phrase is indefinite (1) because a person of skill in the art would not know the "starting point and ending point" of the influence of pH to the granule and (2) because the specification is purportedly silent as to the specific influence on pH (increase, decrease, neutral) and the specific place within the digestive tract that the pH effect takes place are meritless. (Def.'s Resp. Br. at 27-28.) The fact that a claim does not identify a comparator does not mean that a term is indefinite. *Alcon Research Ltd. v. Barr Labs. Inc.*, No. 09-CV-0318-LDD, 2011 WL 6180032, at *18-19 (D. Del. Dec. 13, 2011) (rejecting argument that the term "enhancing the chemical stability" is indefinite because there is no appropriate comparator ("enhanced [chemical stability] over what?"); finding that one of ordinary skill in the art would understand the term to mean "using the invention must increase the chemical stability . . . as compared to not using the invention.").

In any event, one of skill in the art would understand that "permits to obtain reduced pH influence in the digestive tract" describes a fundamental characteristic of the tablet – that the tablet contains coated drug granules to protect the drug (*i.e.*, reduce the influence) from the acidic pH of the stomach. This limitation does not require any measurement of pH as suggested by Mylan. (Byrn Second Supp. Decl. at ¶4.)

In sum, Mylan fails to meet its burden that the term is indefinite, and this Court should adopt Plaintiffs' proposed construction.

C. The Terms "Permits To Obtain Reduced pH Influence In The Digestive Tract" And "Permits To Obtain . . . Reduced Influence Of Viscosity" Are Permissible Functional Limitations In A Composition Claim

Mylan also rehashes an indefiniteness argument already considered and rejected by this Court in *Zydus*. Specifically, Mylan contends that the limitations at issue are indefinite because

they improperly import "method" limitations into a claim directed to a "composition." (Def.'s Resp. Br. at 28-29.)

As previously explained by Plaintiffs in *Zydus*, however, this Court has rejected this strategy of accused patent infringers to characterize claims as invalid "hybrid" claims. In *Ricoh Co., Ltd. v. Katun Corp., PNA*, 486 F. Supp. 2d 395, 402 (D.N.J. 2007), this Court noted that "[i]n almost all cases [where the accused infringer claims that the patent claim is invalid because it is an improper hybrid claim under IPXL], district courts have held that the suspect claims did not cover both an apparatus and a method, but rather were apparatus claims containing functional limitations." Mylan's argument suffers from the same fatal flaws.

Mylan does not dispute that the claim as a whole is directed to a composition, similar to the apparatus claims addressed in *Ricoh*. (Def.'s Resp. Br. at 28.) But the limitations "permits to obtain reduced pH influence in the digestive tract and reduced influence of viscosity" are not directed to methods. To the contrary, these limitations describe the functionality of the composition. Since it is permissible for claim language to define a composition by what it does rather than by what it is, this Court should reject Mylan's argument, just as it did in *Zydus*. *See id*. (citing *In re Schreiber*, 128 F.3d 1473, 1478 (Fed. Cir. 1997)).

III. The Court Should Reject Mylan's New Argument Based on the '994 File History: The "Enteric Coating Agent" And "Sustained-Release Agent" Need Not Have Separate And Distinct Claim Constructions

Mylan's responsive brief cites to newly-identified intrinsic evidence with respect to the relationship between the "enteric coating agent" and "sustained-release agent." (Def.'s Resp. Br. at 14.) Mylan now argues that, when the patentee distinguished the '212 prior art from the '994 invention during prosecution (because that prior art did not disclose the use of an "enteric coating agent" in combination with "a sustained-release agent"), the patentee somehow took the position

that "both of these agents mean different things." (*See id.*) There is no support for Mylan's re-interpretation of the file history; Mylan cannot point to any express statements by the patentee that reflect this purported position.

Mylan critiques Takeda's claim constructions (that are lifted directly from the specification) because they allow for both the "enteric coating agent" and the "sustained-release agent" to be methacrylate copolymers. As Mylan would have it, no given methacrylate copolymer can ever act as both an "enteric coating agent" and a "sustained-release agent" – *i.e.*, Mylan's position that "both of these agents mean different things." But Mylan fails to take into account the fact that excipients can have multiple functions depending on the context in which the excipients are used. (Byrn Second Supp. Decl. at ¶19.) For example, as explained in Plaintiffs' responsive claim construction brief, scientific references expressly teach that Eudragit L30D-55 – a methacrylate copolymer that Mylan contends can only be an "enteric coating agent" – can be a "sustained-release agent." (Pls.' Resp. Br. at 7-8; Byrn Second Supp. Decl. at ¶20.) Stated differently, a specific methacrylate copolymer can act as both an "enteric coating agent" and a "sustained-release agent."

In essence, it is Mylan's contention that Takeda's proposed claim constructions do not allow one of skill in the art to distinguish between an "enteric coating agent" and a "sustained-release agent." Mylan is wrong. One of skill in the art would know if any given methacrylate copolymer is known (1) just as an enteric coating agent; (2) just as a "sustained-release agent" and/or (3) as both. Thus, Takeda's proposed claim constructions do not collapse "enteric coating agent" and a "sustained-release agent" into a "generic class of compounds" without "proffering any distinguishing meaning between the two," as Mylan argues. (Def.'s Resp. Br. at 14.)

IV. Plaintiffs' Expert Did Not Concede That A 10% Standard Of Error Was Not Universally Accepted During The 1998-1999 Timeframe

Not content to mischaracterize Dr. Byrn's testimony as to "enteric coating layer," *see supra*, Mylan likewise butchers his deposition testimony as to "average particle size." In an attempt to overturn this Court's construction of that term in *Zydus*, Mylan asserts that Dr. Byrn conceded there was no universally accepted deviation for laser diffraction in the 1998-1999 timeframe. (Def.'s Resp. Br. at 7; Mumper Supp. Decl. at ¶¶12-13.) Not so.

Dr. Byrn did testify that the known standard of error for particle size measurement was much larger than 10% prior to 1999. But Dr. Byrn's testimony was not limited to the 1998-1999 timeframe, as Mylan would have it. (Byrn Second Supp. Dec. at ¶¶27-28.) Because Mylan's questions relating to measurement error were open-ended as to time (*i.e.*, "prior to 1999"), Dr. Byrn's testimony captured his understanding of those skilled in the art from time periods well before 1999 (*e.g.*, 1980s, early 1990s). (*Id.*; *see also* Byrn Second Supp. Decl. at ¶23 (Dr. Byrn has expertise in average particle size measurements since the early 1980s).)

Instead, as made clear during Dr. Byrn's deposition, the 10% standard of error disclosed in the Snorek article and the USP reflects the general understanding that a person of ordinary skill in the art had during the relevant 1998-1999 time period. (***Ex. 35***, Byrn Dep. Tr. 179:10-16 ("Although [persons skilled in the art] couldn't go to [the USP or Snorek], they would come out with the same analysis . . . my opinion is that 10 percent is a conservative number based on all of my analysis. I think that's what a person skilled in the art would come up with."); *see also* Byrn Second Suppl. Decl. ¶29.)

In short, just as with "enteric coating layer," Dr. Byrn's testimony in relation to "average particle size," when placed in proper context, is utterly consistent with his prior testimony and Takeda's proffered claim constructions.

CONCLUSION

Should the Court choose to entertain Mylan's new arguments introduced in its responsive brief, Plaintiffs submit that this Court should adopt Plaintiffs' proposed constructions, which are consistent with the intrinsic evidence and based on the ordinary meanings of the disputed claim terms, as understood by those of skill in the art.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that true copies of the foregoing Plaintiffs' Reply Claim Construction Brief and all supporting documents were caused to be served on July 6, 2012 via email and the ECF system upon all counsel of record.

By: *s/ John E. Flaherty*
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